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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,801

10/17/2003

Matthew S. Solar

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27572 7590 02/06/2008
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EXAMINER

KISH, JAMES M

ART UNIT	PAPER NUMBER
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3737

MAIL DATE	DELIVERY MODE
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02/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/688,801

Applicant(s)

SOLAR ET AL.

Examiner

James Kish

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-43,45-70 and 76-103 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10,11,22,25-30,36,49,52-57,64-66,68-70,76-90 and 94-103 is/are allowed.
- 6) ☒ Claim(s) 1-5,8,9,12-21,23,24,31-35,37-43,45-48,50,51,58-63,67 and 91-93 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/4/08</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed January 4, 2008 have been fully considered but they are not persuasive.

The Section 103(a) rejection based on Allen in view of Kraus has been removed and incorporated in the Section 103(a) rejection based on Allen in view of Vilsmeier, further in view of Kraus. A response to the Applicant's assertion that this would provide for inoperability of the references is described below.

Allen describes a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has at least a portion that is spherical and defines a surface for cooperating with a tool for securing the second portion 14 to the bone (column 5, lines 1-19). Preferably, the anchor should be screwed into the bone, rather than driven with an impact tool to lessen the chance of fracturing the bone (column 7, lines 40-52). Where the anchor is a screw, preferably an indentation in the shape of a polygon recess to receive an allen wrench is located in marker 12. Allen states that it is very important to locate the exact center of the marker (column 6, lines 61-68). However, there is no means provided for locating the exact center with the localization system. While Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. A "funnel configuration" is used to access precisely the center point of the landmark with a point (column 7, lines 20-47).

Therefore, the conical divot of Vilsmeier is being combined with the teachings of Allen in order to provide for the deficiency of Allen having failed to provide a method or associated feature to locate the exact center of the sphere. The Applicant's argument's regarding the interchangeability of the markers is of no relevance to the features being combined to solve the problem arising in Allen. Furthermore, Applicant's argument that Allen does not require direct contact with the fiducial is erred. As stated in the previous Office Action, "Allen discloses registering an external coordinate system B of a robotic arm with an internal coordinate system A. This is accomplished by touching the tip of the robotic arm on the fiducial implant (column 14, lines 28-53)." The possibility that the combination of these features of Allen and Vilsmeier would cause both inventions to be inoperable due to the fact that Allen's device could no longer be screwed into the bone if a conical divot replaced the hexagonal divot has been discussed in the previous Office Action, dated October 9, 2007. Regarding this argument, Kraus has been incorporated and is discussed below.

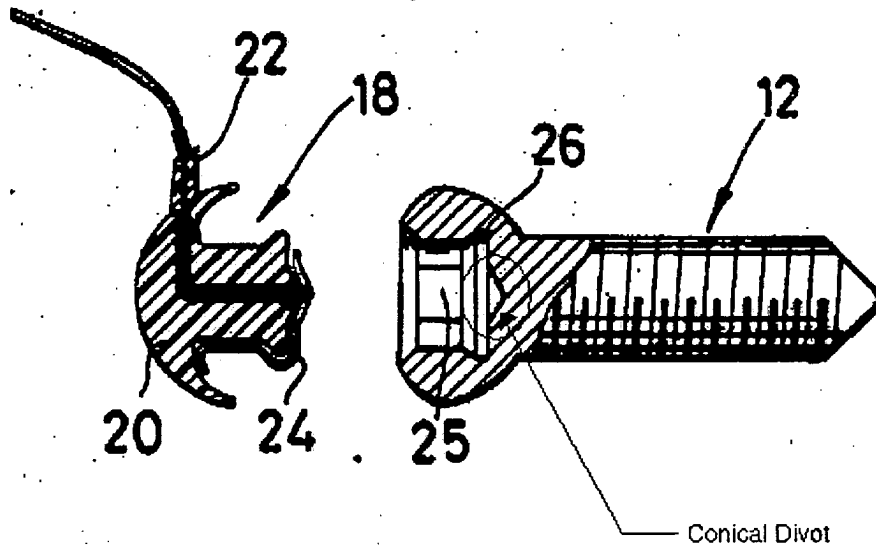


Image 1.

Image 1 above illustrates Figure 4 of Kraus. As demonstrated above, there is a hexagonal portion 25 for engagement with an allen wrench. Also illustrated is a conical divot at the base of the hexagonal portion. Therefore, Kraus teaches the ability of a fiducial marker/bone screw to incorporate both claimed features in one apparatus.

Regarding Applicant's argument that none of the above mentioned prior art, nor Reed teaches a bone screw shaft including an externally unthreaded portion separating an externally threaded portion from an imageable fiducial locator head, as recited in claim 91, the Examiner points the Applicant to any of Figures 2, 5, 20A, 23 and 24 of Reed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8-9, 12-17, 19-21, 23-24, 32-35, 40-44, 46-48, 50-51, 59-63 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Vilsmeier (US Patent No. 6,351,659), and further in view of Kraus. Allen discloses a fiducial implant for the human body that is detectable by imaging systems (see Abstract). A first portion 12 has at least a portion, which is spherical and defines a surface for cooperating with a tool for securing the second portion 14 to the bone (column 5, lines 1-19). This first portion is preferably hollow and can be filled with a gel having various desired dopants, depending on the imaging system (column 7, lines 32-39). Preferably, the anchor should be screwed into the bone, rather than driven with an impact tool to lessen the chance of fracturing the bone (column 7, lines 40-52). However, Figure 1a shows an embodiment wherein second portion 14 is not threaded and would need to be driven into the bone by a means other than screwing. Where anchor is a screw, preferably an indentation in the shape of a polygon recess to receive an allen wrench is located in marker 12. The use of an allen wrench is due to the increased symmetrical integrity provided over the use of the cross shaped receptor site for a Phillips screw driver or a single groove receptor site for a standard screw driver (column 7, lines 53-61). However, if this symmetry was not important, it would be

obvious to use one of these other screwdriver shapes. A trocar is placed at the anchoring site and the marker is placed within the trocar, thereby providing a guide collar about the marker (column 8, lines 1-9). Allen discloses registering an external coordinate system B of a robotic arm with an internal coordinate system A. This is accomplished by touching the tip of the robotic arm on the fiducial implant (column 14, lines 28-53). While Allen discloses a divot in the top of the marker portion 12, it is not described as a divot for placement of a localization instrument. Vilsmeier teaches a localization system with markers that facilitates easy localization by a computer/camera unit. The system has spherical markers provided with a reflective coating (column 4, lines 24-28). Furthermore, a "funnel configuration" is used to access precisely the center point of the landmark with a point. Due to the landmark's funnel configuration they can be localized even after they are covered by a cloth. See column 7, lines 20-47, as well as Figure 8. Also, column 12, lines 1-11 teach the ease of sterilization of the markers. Once the markers have been sterilized they would obviously have a coating of sterilizing agent. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a funnel configuration, as taught by Vilsmeier, in the fiducial system of Allen because Allen states that it is very important to locate the exact center of the marker (column 6, lines 61-68). However, there is no means provided for locating the exact center with the localization system. Vilsmeier states that the funnel configuration allows the surgeon to access precisely the center point of the landmark with the pointer (column 7, lines 20-47). Kraus teaches a bone screw with a substantially spherical head portion and a bone screw shaft. The head is provided with

an inlet for engagement with an allen wrench type screwdriver. At the base of the inlet is provided a conical receptacle that provides a point located at the center of the circular head portion when viewed in the axial direction. Kraus teaches a apparatus that incorporates the structural limitations necessary to combine Allen with Vilsmeier. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use Kraus as a teaching reference to incorporate the center point localization of a spherical marker head, as taught by Vilsmeier, while also allowing an allen wrench to fix the screw into the bone, as taught by Allen. Furthermore, Kraus provides a cap that protects the inside of the slot and provides a fully spherical marker head, preventing it from catching and causing discomfort to the patient.

Claims 18, 37-39, 45 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Vilsmeier and Kraus, further in view of Reed (US Patent No. 5,968,047). Allen in view of Vismeier and Kraus is described above. However, these bone screw portions do not provide an unthreaded portion. Reed discloses a sterile fixation device with a threaded portion and an unthreaded portion with an aperture, or groove **112** (see Figure 23). This device is made completely sterile. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a threaded and unthreaded portion as taught by Reed, as well as create a sterile bone fixation device in order to create an immunologically acceptable joint with the bone (column 2, lines54-55).

Claims 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Vilsmeier and Kraus, further in view of McCrory et al. (US Patent No. 6,333,971). Allen in view of Vilsmeier and Kraus is described above. However, these bone screw portions do not provide an unthreaded portion. McCrory provides a base portion of an imageable fiducial marker assembly having both a threaded portion and an unthreaded portion. The threaded portion **32**, as illustrated in Figure 2A and 2B, has a small maximum diameter than that of the unthreaded portion, providing for a depth stop. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a narrower threaded portion to separate the fiducial marker from the surface of the patient's skull/bone.

Claims 31 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Vilsmeier and Kraus, further in view of Franck et al. (US Patent No. 6,273,896). Allen in combination with Vilsmeier and Kraus is described in the above rejection. However, none of these references clearly teaches a headband. Franck teaches as an alternative to implanting markers to instead use an elastic headband to place them. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a cap to place on the head of the bone screw/fiducials of Allen, Vilsmeier and Kraus in order provide an alternative method of placing the markers that is less invasive for the patient.

Allowable Subject Matter


Claims 10-11, 22, 25-30, 36, 49, 52-57, 64-66, 68-70, 76-90 and 94-103 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Kish whose telephone number is 571-272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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